Pandemic Influenza Vaccine Program Status

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mRNA-1018: Clinical Development Status

- Moderna's seasonal influenza vaccine (mRNA-1010) currently in late-stage development, pivotal phase 3 efficacy trial is ongoing
- Development of our pandemic influenza vaccine (mRNA-1018) began in 2023; a dose ranging phase 1/2 clinical trial is complete and preliminary results are encouraging; complete data is currently being analyzed and planned for presentation at scientific congress later this year
- A Phase 3 study is planned to start later this year, to enable licensure based on established regulatory guidance. [1, 2]

1 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-data-needed-support-licensure-pandemic-influenza-vaccines
2 https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/pandemic-influenza/vaccines-pandemic-influenza

mRNA-1010-P304: Seasonal Influenza Efficacy Study in Adults 50+ years of age

Design
Randomized, observer-blind, active-controlled study

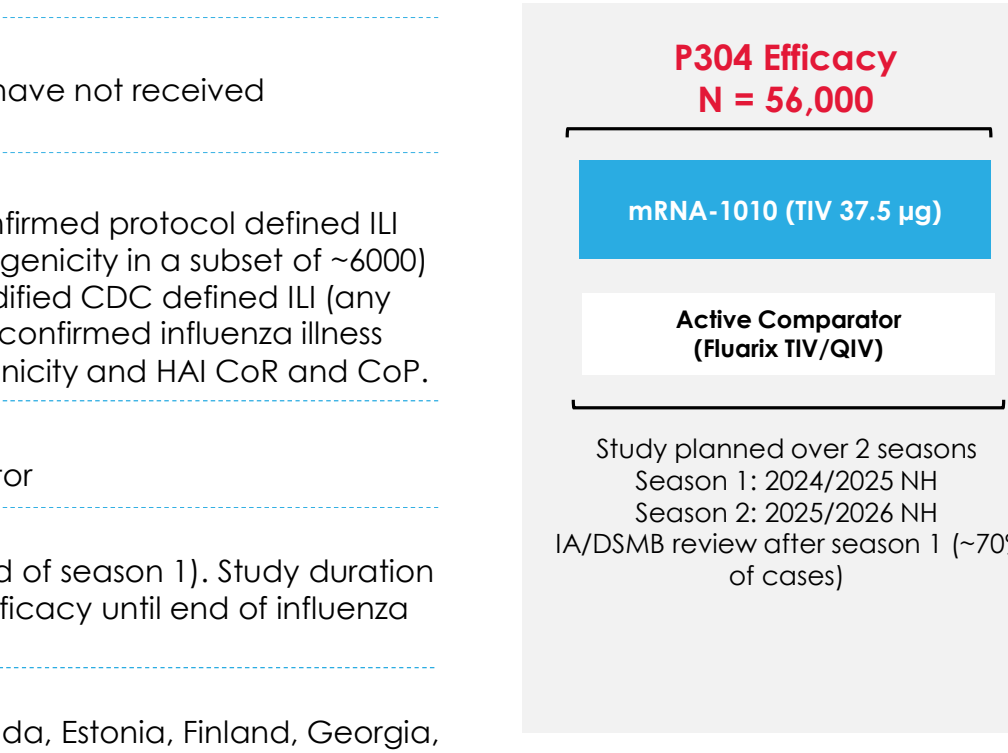
Participants
56,000 medically stable adults 50+ years old who have not received influenza vaccination in the past 6 months

Endpoints
Primary: rVE to prevent first episode of RT-PCR–confirmed protocol defined ILI caused by any strain and safety (including reactogenicity in a subset of ~6000)
Secondary: rVE to prevent RT-PCR–confirmed modified CDC defined ILI (any strain), noninferior/superior rVE to prevent RT-PCR–confirmed influenza illness (similar/antigenically matched strains), immunogenicity and HAI CoR and CoP.

Vaccination schedule
Randomization to mRNA-1010 or active comparator

Duration
Study planned over 2 seasons (IA/DSMB at the end of season 1). Study duration per participant up to 8 months (day 181 safety/efficacy until end of influenza season)

Site location
Northern hemisphere (US, Belgium, Bulgaria, Canada, Estonia, Finland, Georgia, Germany, South Korea, Taiwan, United Kingdom)



RT-PCR, reverse transcription polymerase chain reaction; rVE; relative vaccine efficacy.

Clinicaltrials.gov. A Study of mRNA-1010 Seasonal Influenza Vaccine in Adults 50 Years Old and Older. 2022. https://clinicaltrials.gov/ct2/show/NCT05566639

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mRNA-1018-P101 Study Design (NCT05972174)

Design
Randomized, dose-ranging, observer-blind study of the safety, reactogenicity and immunogenicity of mRNA-1018 in healthy adults

Number of participants
~1,500 adults ≥18 years of age randomized

Objectives
Primary objective: To evaluate the safety and tolerability of group 1 and 2 HA and HA+NA mRNA pandemic influenza vaccines at various dose levels in healthy adults 18+

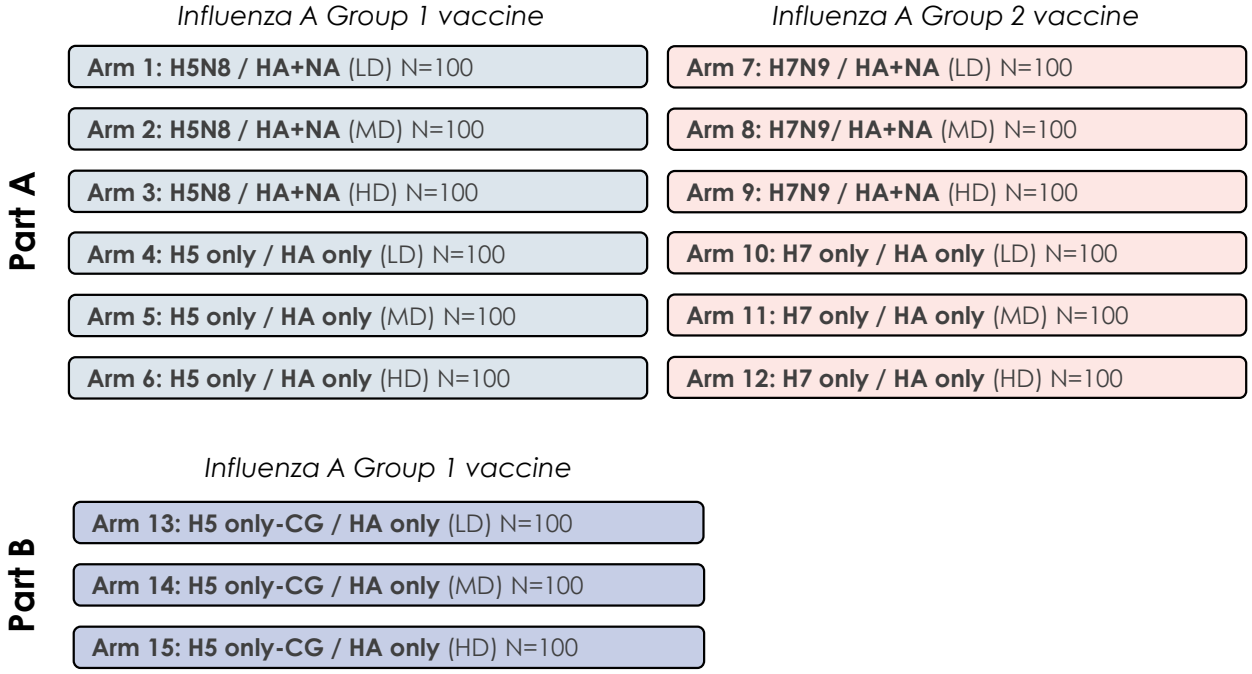
Secondary objectives: to evaluate humoral immune response by haemagglutination inhibition (HAI), microneutralization (MN), NA inhibition (NAI), and cellular immunogenicity (CMI)

Vaccination schedule
Two doses, 21 days apart

Duration
Participants followed up for 6 months after last dose

Location
United States and United Kingdom

Phase 1/2 trial design



H5 strains in the study are part of the same clade (2.3.4.4b) and antigenically similar to the viruses currently circulating in the U.S.

Thank you

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